This Program Announcement expires on November 27, 2002, unless reissued.

# INNOVATIONS IN BIOMEDICAL INFORMATION SCIENCE AND TECHNOLOGY: SBIR/STTR INITIATIVE

Release Date: June 29, 2000

PA NUMBER: PA-00-118

National Cancer Institute
National Center for Complementary and Alternative Medicine
National Center for Research Resources
National Eye Institute
National Human Genome Research Institute
National Heart, Lung, and Blood Institute
National Institute on Aging
National Institute of Alcohol Abuse and Alcoholism
National Institute of Allergy and Infectious Diseases
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute on Drug Abuse
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National Institute of Dental and Craniofacial Research
National Institute of Diabetes and Digestive and Kidney Disease
National Institute of Environmental Health Sciences
National Institute of General Medical Sciences
National Institute of Mental Health
National Institute of Neurological Disorders and Stroke
National Institute of Nursing Research
National Library of Medicine

Application Receipt Dates: November 27, March 27, and July 27 annually (The solicitation begins with the November 27, 2000, receipt date and ends with the November 27, 2002, receipt date.)

## PURPOSE

Participating Institutes and Centers of the National Institutes of Health invite applications for innovative research in biomedical information science and technology to promote the progress of biomedical research.

There exists an expanding opportunity to speed the progress of biomedical research through the power of computing to manage and analyze data and to model biological processes. The NIH is interested in promoting research and developments in biomedical information science and technology that will support rapid progress in areas of scientific opportunity in biomedical research. As defined here biomedical computing or biomedical information science and technology includes, database design, graphical interfaces, querying approaches, data retrieval, data visualization and manipulation, data integration through the development of integrated analytical tools, synthesis, and tools for electronic collaboration, as well as computational research including the development of structural, functional, integrative, and analytical models and simulations.

This program will use the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) mechanisms and will be run in parallel with a program of identical scientific scope that will use the newly-created Phased Innovation Award mechanism (TPA-00-109). The SBIR and STTR applications received in response to this announcement will have the opportunity for expedited transition of successful technology research into an expanded development phase and will be subject to cost and duration limits comparable to the parallel Phased Innovation Award applications.

This program announcement must be read in conjunction with the Omnibus Solicitation of the Public Health Service for Small Business Innovation Research Grant Applications (PHS 99-2), and the Omnibus Solicitation of the National Institutes of Health for Small Business Technology Transfer Grant Applications (PHS 99-3). All of the instructions within the Omnibus Solicitations apply with the following exceptions:

- Additional review considerations

- Opportunity for 2 years of Phase I support

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010", a PHS-led national activity for setting priority areas. This program announcement (PA), “Innovations in Biomedical Information Science and Technology:
SBIR/STTR Initiative”, is related to one or more of the priority areas.
Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/ .

ELIGIBILITY REQUIREMENTS

Eligibility requirements for SBIR and STTR are described in the NIH Omnibus Solicitation for SBIR/STTR grant applications.

MECHANISM OF SUPPORT

This PA will expire two years from the initial receipt date as indicated by the dates on the front of this solicitation. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant. Except as otherwise stated in this program announcement, awards will be administered under PHS grants policy as stated in the NIH Grants Policy Statement, NIH Publication No99-8, October 1998.

A. FAST-TRACK APPLICATIONS. Applications may be submitted for the FAST-TRACK review option. Information on the FAST-TRACK process may be found at: http://grants.nih.gov/grants/funding/sbir.htm. Applications will be accepted only on the receipt dates listed on the first page of this document.

To be eligible for the FAST-TRACK option, the Phase I (R41/43) application must include well defined quantifiable milestones that will be used to judge the success of the proposed research, as well as a credible development plan for the Phase II (R42/44) application. The FAST-TRACK must have a section labeled Milestones at the end of the Research Plan for Phase I R41/43. This section must include well-defined quantifiable milestones for completion of Phase I R41/43, a discussion of the suitability of the proposed milestones for assessing the success in Phase I R41/43, and a discussion of the implications of successful completion of these milestones on the proposed Phase II R42/R44.

Applications submitted through the FAST-TRACK option are subject to the same direct costs limits per year as when submitted outside of the FAST-TRACK option: Phase I R41/43, not to

exceed $100,000 per year total direct costs excluding subcontractor indirect costs; Phase II R42/44, no dollar limit. However, for this solicitation the total duration (Phase I plus Phase II applications) cannot exceed four years. In any case, the Phase I applications cannot exceed two years duration.

Applications over $500,000. Although the Phase II application has no official budgetary limit, applications requesting in excess of $500,000
dollars direct costs in any single year of the grant period require prior approval before submission. Applicants who plan to submit a Phase II SBIR/STTR application requesting $500,000 or more in any year are advised that it is important that they contact program staff listed under INQUIRIES as they begin to develop plans. Applications requesting more than $500,000 received without prior staff contact may be delayed in the review process or returned to the applicant without review (NIH GUIDE, Volume 22, Number 45, December 17, 1993)

B. INDIVIDUAL PHASE I APPLICATIONS. Phase I applications in response to this PA will be funded as Phase I SBIR Grants R43 or STTR Grants R41 with modifications as described below following the directions for Phase I SBIR/STTR applications as described in the NIH Omnibus Solicitation. The NIH Omnibus SBIR Solicitation is available on the Internet at: http://grants.nih.gov/grants/funding/sbirsttr1/index.htm. The NIH OMNIBUS STTR Solicitation is available at: http://grants.nih.gov/grants/funding/sbirsttr1/index.htm

A limited number of hard copies of the NIH Omnibus SBIR and STTR
Solicitations are available from:

PHS SBIR/STTR Solicitation Office
13685 Baltimore Avenue
Laurel, MD 20707-5096
Telephone: 301-206-9385
FAX: 301-206-9385
Email: a2y@cu.nih.gov

Project Period and Amount of Award. Because the length of time and cost of research involving advanced information science and technology projects often exceeds that normally awarded for SBIR/STTR grants, NIH will entertain well-justified Phase I applications with a project period up to two years and a budget not to exceed $100,000 per year direct cost (maximum of $200,000 direct costs for to 2 years excluding subcontractor indirect costs).

Page Limitations. The requirements for normal Phase I applications apply (see NIH OMNNBUS Solicitation).

C. INDIVIDUAL PHASE II APPLICATIONS

Phase II applications in response to this PA will be awarded as Phase II SBIR Grants R44 or STTR Grants R42 with modifications as described below. Phase II applications in response to this PA will only be accepted as competing continuations of previously funded NIH Phase I SBIR/STTR awards. The Phase II application must be a logical extension of the Phase I research.

Applications for Phase II awards should be prepared following the instructions for NIH Phase II SBIR/STTR applications. The Phase II SBIR instructions and application may be found on the Internet at: http://grants.nih.gov/grants/funding/sbir2/index.htm
The Phase II STTR instructions and application may be found on the Internet at: http://grants.nih.gov/grants/funding/sttr2/index.html

Project Period and Amount of Award. Because the length of time and cost of research often exceeds that normally awarded for SBIR grants, NIH will entertain well-justified Phase II applications for this SBIR/STTR award with a project period up to three years with no budget limitation.

Applications over $500,000. Although the Phase II application has no official budgetary limit, applications requesting in excess of $500,000 dollars direct costs in any single year of the grant period require prior approval before submission. Applicants who plan to submit a Phase II SBIR/STTR application requesting $500,000 or more in any year are advised that it is important that they contact program staff listed under INQUIRIES as they begin to develop plans. Applications requesting more than $500,000 received without prior staff contact may be delayed in the review process or returned to the applicant without review (NIH GUIDE, Volume 22, Number 45, December 17, 1993)

BACKGROUND

Computing and computational tools have become increasingly important in enabling progress in biomedical research. In recognition of the critical role computing will play in biomedical research, the NIH Director commissioned a Working Group on Biomedical Computing to:

Investigate the needs of NIH-supported investigators for computing resources, including hardware, software, networking, algorithms, and training. It should take into account efforts to create a national information infrastructure, and look at working with other agencies (particularly NSF and DOE) to ensure that the research needs of the NIH-funded research community are met.

It should also investigate the impediments biologists face in utilizing high-end computing, such as a paucity of researchers with cross-disciplinary skills. The panel should consider both today's unmet needs and the growing requirements over the next five years (a reasonable horizon for extrapolating the advances in the rapidly changing fields of computing and computational biology).

The result of the deliberations of the Working Group on Biomedical Computing is a report entitled "The Biomedical Information Science and Technology Initiative" (BISTI) which can be accessed at the following site: http://www.nih.gov/welcome/director/060399.htm. A critical recommendation of the BISTI is that the NIH should provide additional resources and incentives for basic research to provide adequate support for those who are inventing, refining, and applying the tools of biomedical computing. The promotion of the interface of biomedical information science and technology with biomedical research should result in new digital and electronic tools that will have substantial impact on broad areas of biomedical research.

The Institutes and Centers of the NIH acknowledge the wisdom of this recommendation and are offering support to small business through the current solicitation for fundamental research in biomedical information science and technology, as well as for the development of new informatics and computational tools and technologies.

RESEARCH GOALS AND OBJECTIVES:

This solicitation targets support for fundamental research in biomedical computing science and technology as well as the development and application of new biocomputing tools or technologies for a particular area(s) of scientific opportunity in biomedical research. Programs may target one or multiple areas of biomedical computing that will enable progress in biomedical research. Specific research areas solicited in informatics or computational science include but are not limited to:

- Tools for data collection
- Tools for archiving large data sets
- Research on databases, querying approaches, and information retrieval

- Research on data visualization
- Analysis tools for interpretation of large data sets
- Computing algorithms and new analysis and statistical methodologies for social science research related to areas of biomedical interest, such as population aging
- Research on new approaches to data integration
- Development of platform-independent translational tools for data exchange
- Research on the development of models or simulation environments
- Development of models or simulation environments
- Tools or models to promote interoperability
- Development of web-based linkage tools for data sharing
- Tools for electronic communication

Areas of biomedical research likely to be critically dependent on biocomputing advances include but are not limited to:

- Behavioral science
- Biological rhythms
- Biomedical imaging
- Cell biology
- Clinical research
- Clinical trials
- Developmental biology
- Drug design at the molecular and cellular levels
- Dynamic modeling of retirement
- Dynamic modeling of health, chronic disease, and disablement
- Endocrinology
- Environmental science
- Epidemiology
- Genetics
- Genomics
- Immunology/inflammation
- Medical genetics
- Morphology
- Neurobiology and cognitive science
- Pharmacology
- Physiology
- Population biology
- Structural biology

- Substance abuse research
- Surgery and virtual tools
- Temporal patterns

Projects must span the interface of biomedical research and biomedical information science and technology. Applications will be expected to demonstrate fundamental understanding and adequate expertise in both the relevant areas of information science and technology and biomedical research. Cross-disciplinary collaborations are strongly encouraged. Applications will also be expected to address the anticipated enabling aspects of the research or development proposed in the context of the targeted area of opportunity in biomedical research the research is expected to benefit.

Given the expanding needs in biomedical research for advances in a variety of areas of information science and technology, the approaches and technologies proposed under this announcement should ultimately be generalizable, scalable, extensible, interoperable and use sophisticated computational resources. The projects should take in to account the needs of the biomedical research community that will be the ultimate end users of the products of the research. The projects should also address plans for ensuring the dissemination of useful products of the research, including approaches, technologies and tools, to the relevant research and user communities. The informatics and computational research proposed should be future-oriented, fill an area of need or projected need, and seek to exceed the current state-of-the-art.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the “NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research”, which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513) and in the NIH Guide for Grants and Contracts, Volume 23, Number 11, March 18, 1994, and is available on the Internet at http://grants.nih.gov/grants/guide/notice-files/not94-100.html .

Investigators also may obtain copies of the policy from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of NIH that children (i.e., individuals under the age of 21) must be included in all human subjects research conducted or supported by the NIH unless there are scientific or ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html .

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary for the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

APPLICATION PROCEDURES

OMNIBUS SOLICITATIONS for both the SBIR and STTR programs are available electronically through the NIH, Office of Extramural Research Small Business Funding Opportunities Web site at http://grants.nih.gov/grants/funding/sbir.htm. Hard copies, subject to availability, may be obtained from the PHS SBIR/STTR Solicitation Office at 301-206-9385 (phone); 301-206-9722 (fax); or a2y@cu.nih.gov (email). Helpful information for preparing the application can be obtained on the Web at http://grants.nih.gov/grants/funding/sbirgrantsmanship.pdf .

Applications are to be submitted on the grant application forms PHS 6246-1 (1/99) (SBIR) and PHS 6246-3 (STTR) (3/99) located in the back pages of the OMNIBUS SOLICITATIONS, and will be accepted at the application deadlines indicated on the first page of this document.

THE TITLE AND NUMBER OF THIS PA MUST BE TYPED IN LINE 2 ON THE FACE PAGE OF THE APPLICATION.

The OMNIBUS SOLICITATIONS give the normal levels of support and period of time for SBIR and STTR Phase I and II awards. However, these award levels are guidelines and not ceilings. Therefore, larger budgets with longer periods of time may be requested if required to complete the proposed research. As stated under MECHANISM OF SUPPORT section, Phase I plications submitted in response to this PA can have a project period of up to two years and a budget not to exceed $100,000 per year direct cost excluding subcontractor indirect costs.

An annual meeting of all investigators funded through this program will be held to share progress and research insights that may further progress in the program. Applicants should request travel funds in their budgets for the principal investigator and one additional senior investigator to attend this annual meeting

The second year of the Phase I budget should be included on the Budget Justification page using categorical totals if costs deviate significantly from the first year of the budget with narrative justifications for the increase(s). If the second year simply escalates due to cost of living factors, a statement to that effect with the escalation factor should be included rather than categorical totals. Phase II applications submitted in response to this PA have no budget limitations. The total duration (Phase I and Phase II application) cannot exceed four years. To apply for the FAST-TRACK option, applications for both Phase I and Phase II must be submitted together according to the instructions for FAST TRACK applications as described in the OMNIBUS SOLICITATIONS. The Phase I application must specify clear, well-defined quantifiable milestones that should be achieved prior to Phase II funding. Milestones should be located in a separate section at the end of the Research Plan of the Phase I and should be indicated in the Table of Contents. Failure to provide measurable milestones and sufficient detail may be sufficient reason for the peer review committee to exclude the Phase II application from FAST-TRACK review. If so, at a later date, the applicant may apply for Phase II support through normal application procedures.

An additional requirement of the FAST-TRACK mechanism is the Product Development Plan. The small business must submit a concise Product Development Plan (limited to five pages) as

an Appendix to the Phase II application addressing the four areas described in the instructions for FAST-TRACK applications in the OMNIBUS SOLICITATIONS. In the event that an applicant feels that technology is too proprietary to disclose, applicants at a minimum should provide a demonstration (e.g., results) of the capabilities of the proposed technology.

The completed and signed original application and two legible and signed copies must be sent or delivered in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE
ROOM 1040 - MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

Applications must be received by the receipt dates listed at the beginning of this program announcement.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by the CSR for completeness and by the NIH program staff for responsiveness. Applications not adhering to application instructions described above and those applications that are incomplete or non-responsive as determined by CSR or by NIH program staff will be returned to the applicant without review.

Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the NIH in accordance with the review criteria stated below. As part of the initial merit review, all applicants will receive a written critique and may undergo a process in which only those applications deemed to have the highest scientific merit generally the top half of the applications will be discussed, assigned a priority score, and receive a second level review by the appropriate Institute or Center Advisory Board.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments, reviewers will be asked to discuss the following aspects of the application to judge the likelihood that the proposed

research will have a substantial impact on the pursuit of these goals. Each of the following criteria will be addressed and considered in assigning the overall score, weighing them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance.
o Does this study address an important problem?
o Are the results of the study likely to enable a compelling area of biomedical research?
o If the aims of the application are achieved, how will scientific knowledge be advanced?
o What will be the effect of these studies on the concepts or methods that drive this field?
o To what degree does the research or development of technologies or tools support the needs of the targeted biomedical research community?
o For systems intended for clinical research or use the additional criteria will be considered:
? To what degree is the approach, technology, or tool appropriate for clinical research and likely to have utility in a clinical setting?
? Do the applicants adequately address such issues as the protection of patient information and confidentiality?

2. Approach.
o Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?
o Does the applicant acknowledge potential problem areas and consider alternative tactics?
o What is the time frame for developing the proposed approaches, tools, or technologies and suitability of this time frame for meeting the needs of the relevant biomedical research community's needs?
o How easy will it be to use the proposed approach, tool, or technology?
o Are the plans for dissemination of the proposed endpoints, tools or technologies of the project adequate?

3. Milestones.
o How appropriate are the proposed milestones against which to evaluate the demonstration of feasibility for transition to the R42/R44 development phase?

4. Innovation.
o Does the project employ novel concepts, approaches or method?

o Are the aims original and innovative?
o Does the project challenge existing paradigms or develop new methodologies or technologies?
o Does the project adequately address end user needs?
o Will there be additional application opportunities for the approach, technology or tool proposed?
o Does the project use high-end computing?

5. Investigator.
o Is the investigator appropriately trained and well suited to carry out this work?
o Does the project team have adequate expertise in both the areas of biomedical information science and technology and biomedical research?
o Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

6. Environment.
o Does the scientific environment in which the work will be done contribute to the probability of success?
o Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?
o Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will be reviewed with respect to the following:

o The adequacy of plans to include both genders, minorities and their subgroups, and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The reasonableness of the proposed budget and duration in relation to the proposed research.

o The adequacy of the proposed protection for humans, animals, and the environment to the extent they may be adversely affected by the proposed project.

Additional scientific/technical merit criteria specific to the objectives of the PA and the mechanism must be included if they are to be used in the review.

AWARD CRITERIA

Applications will compete for available funds with all other approved SBIR and STTR applications. Funding decisions for Phase I will be based on quality of the proposed project as determined by peer review, availability of funds, and program priority. Fast-Track Phase II applications may be funded following submission of the Phase I progress report and other documents necessary for continuation. Phase II applications will be selected for funding based on the initial priority score, NIHs assessment of the Phase I progress and determination that Phase I milestones were achieved, programmatic relevance, the project potential for commercial success, and the availability of funds.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Inquiries or contacts concerning institute-specific technical or financial issues should be directed to the NIH BISTI technical and financial contacts listed at the following Web site: http://grants.nih.gov/grants/bistic/bistic_contacts.cfm .

Inquiries regarding general programmatic issues or notices of intent should be directed to:

Dr. James Cassatt
NIGMS
45 Center Drive
Bethesda, MD 20892-6200
TEL: 301-594-0828
FAX: 301-480-2004
Email: jc12b@nih.gov

Inquiries regarding review matters should be directed to:

Elliot Postow, Ph.D.
Center for Scientific Review
6701 Rockledge Drive
Bethesda, MD 20892
TEL: (301) 435-0911
FAX: (301) 480-2241

Email: postowe@csr.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.394, Cancer Detection and Diagnosis Research. Awards are made under authorization of the Sections 301 and 405 of the Public Health Service Act, as amended (42 USC 241 and 284) and administered under PHS grants policies and Federal Regulations 42 CFR 52 and 45 CFR Part 74 and part 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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